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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,882	12/19/2001	Sheldon Tobe	PT-1949001	8815

23607 7590 06/06/2006

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,882	TOBE, SHELDON	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006 and 15 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21* is/are pending in the application.

4a) Of the above claim(s) *2-8,11-13,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,14,17-19 and 21* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office action is in response to applicant's remarks and amendment of 3/15/2006 and remarks and declaration of 2/9/2006.

Claims 1-19 and 21 are pending in this application. Pursuant to the restriction requirement and applicant's election of record, claims **1, 9-10, 14, 17-19 and 21** will presently be examined to the extent that they read on the elected subject matter. Claims 2-8, 11-13 and 15-16 remain withdrawn from further consideration as being directed to non-elected subject matter.

Applicant is advised of the following. Claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1 if and when claim 1 is allowed. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Applicant is requested to cancel claim 18.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United states before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the

international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9, 14, 17 and 18 are rejected under 35 USC 102(b) as being anticipated by Purcell et al. (US 5,945,449).

Purcell et al. explicitly disclose a sterile calcium-free bicarbonate concentrate comprising 86.87 ± 8.6 g/l NaCl, 2.05 ± 0.2 g/l $MgCl_2$, and 39.69 ± 3.9 g/l $NaHCO_3$ (column 4, lines 52-56). A sterile, diluted solution is also disclosed, wherein 140 ± 14 mM Na, 0.75 ± 0.07 mM Mg, 106.5 ± 10 mM Cl, and 35 mM ± 3.5 HCO_3 are present (column 4, lines 59-63). The concentrate is used in the field of peritoneal dialysis and hemodialysis (column 4, lines 66-67).

It is clearly recognized by the Examiner that instant claim 1 recites, "concentration of bicarbonate [ ] sufficiently low so as to allow preparation of a sterile dialysis solution for continuous renal replacement therapy having a bicarbonate concentrate of 5-27.5 mmol/l." The claim language in independent claims 14 and 17 is similar in that the concentrate is formulated such that the resulting solution has a bicarbonate level within the range of 5-27.5 mmol/l.

However, it must also be recognized that applicant's claims here are directed either to the concentrate per se or a diluted form without any further specificity as to composition makeup. Even though Purcell et al. did not actually dilute their concentrate so that it resulted in 5-27.5 mM HCO_3, Purcell's concentrate is inherently capable of being so diluted. Any bicarbonate-containing concentrate can allow the diluted form to have 5-30 mM HCO_3. This is a necessary property of the concentrate and it cannot be somehow extinguished by the actual diluted solution obtained by Purcell et al. Therefore, since Purcell's sterile, calcium-free concentrate contains 39.69 ± 3.9 g/l $NaHCO_3$, said concentrate would necessarily have been capable of being diluted to provide a solution that contains 5-30 mM HCO_3.

The claim language pertaining to minimizing risk to metabolic complications and continuous renal replacement therapies (CRRT) such as dialysis and hemofiltration are noted, but since Purcell's composition contains the same composition ingredients or composition ingredients that cannot be distinguished from applicant's claimed composition, and since Purcell's composition is suitable for hemodialysis and peritoneal dialysis, such properties would have been necessarily present in Purcell's composition. MPEP 2112, 2112.01.

All of applicant's claim features are thereby met. The claims are anticipated.

Applicant's arguments filed on 3/15/2006 and arguments and declaration filed on 2/9/2006 have been given due consideration but they were deemed unpersuasive.

Applicant/Declarant overestimates the limiting effect of the claim language in excluding prior art such as Purcell et al. The reference by Purcell et al. is applicable because instant claims are too broadly drafted. No amount of scientific or legal argument can get around this fact.

Applicant seems to be arguing that the claims imply a direct dilution of concentrate → solution. Where is the claim language for that interpretation? Where does it say in any of the claims, "take only the concentrate, don't add anything else except water, and dilute only the concentrate to provide for the final solution." Where in the claims is there prohibition to add additional ingredients to formulate the final solution? It is not uncommon in the dialysis art to combine two or more sources to arrive at a final solution.

1. (currently amended) A sterile calcium free low bicarbonate dialysis concentrate composition for continuous renal replacement therapy for use in the preparation of a dialysis solution comprising sodium chloride (NaCl), magnesium chloride (MgCl2), and a concentration of ~~bicarbonate~~ sodium bicarbonate (NaHCO3) sufficiently low so as to allow preparation of a sterile dialysis solution for continuous renal replacement therapy having a bicarbonate concentrateion of 5-~~30~~27.5 mmol/l.

Applicant's claim language, as illustrated in claim 1 above, requires that the concentrate is "for" CRRT, "for use in the preparation of a dialysis solution" (does not say for example, "for use with no other added ingredients except water"), and bicarbonate concentration "sufficiently low so as to allow" the preparation of a dialysis solution for CRRT having bicarbonate concentration of 5-27.5 mmol/l.

Here, Purcell's concentrate can be "for" CRRT, can be "for use" in the preparation of a dialysis solution, and can be diluted to provide a bicarbonate concentration of 5-27.5 mmol/l. Purcell's disclosure therefore meets applicant's claim language since it does not preclude addition of other ingredients to arrive at the final solution. It is applicant who chose to claim the concentrate by describing what a prepared solution is to contain, not what the claimed concentrate contains. Applicant has to abide by the consequence of such patent claim drafting strategy.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9, 14, 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martis et al. (WO 96/01118) in view of Purcell et al.

Martis et al. disclose a peritoneal dialysis solution that comprises:

Dextrose	1.5-4.25 g/dl
Na	100-140 mEq/l
Cl	70-110 mEq/l
Calcium	0.0-4.0 mEq/l
Mg	0.0-4.0 mEq/l
Bicarbonate	20.0-30.0 mEq/l
Weak acid	10-20 mEq/l.

See Martis' claim 7.

Applicant's calcium free feature is met by Martis' clear teaching of 0.0 mEq/l of calcium. Martis' 20-30 mEq/l bicarbonate concentration is expressly within applicant's concentration range. A sterile concentrate or solution is not explicitly disclosed by Martis et al. However, one having ordinary skill in the art would have been motivated to provide a sterile dialysis solution in order to ensure patient safety. Applicant's designation of "concentrate" does not provide sufficient distinguishing weight because there is no specific dilution factor claimed. Even if there were a specific dilution factor claimed, one having ordinary skill in the art would have been motivated to first formulate a concentrate and then dilute the concentrate to the component concentration disclosed and suggested by Martis et al., because concentrates provide the advantage of storage stability and convenience.

Further, the patent by Purcell et al. (US 5,945,449) is cited to establish that one having ordinary skill in the art would have been well aware of the benefit

of using a sterile peritoneal dialysis solution, which is obtained from a sterile dialysis concentrate. See from column 4, line 64 to column 5, line 7.

While the composition makeup in Purcell et al. is different, their disclosure establishes that the level of the ordinary skill in this art would have been such that sterile dialysis concentrate and sterile dialysis solution would have been well within the skill of the ordinary skilled artisan.

Consequently, the ordinary skilled artisan would have been motivated to utilize a sterile dialysis concentrate and prepare a sterile dialysis solution in accordance with Martis' disclosure (e.g., claim 7).

Additionally, because Martis' dialysis solution is biochemically balanced to correct metabolic acidosis (page 4, lines 7-10), applicant's feature of minimizing metabolic complication risks is met. As for the feature of "for continuous renal replacement therapies such as dialysis and hemofiltration," the composition makeup of Martis' dialysis solution and the concentrate suggested thereby would be suitable for such therapies.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.[1]

Applicant's arguments filed on 3/15/2006 and arguments and declaration filed on 2/9/2006 have been given due consideration but they were deemed unpersuasive.

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[1] It is noted that claim 10 is not included in this ground of rejection. The Examiner believes that picking and choosing both the calcium free feature and magnesium concentration feature (Mg = 0.75 ± 0.07 mmol/l) is not fairly suggested from Martis' disclosure as a whole and Martis' specific disclosure of
0-4 mEq/l calcium and 0-4 mEq/l magnesium.

Applicant argues that Martis' "effective bicarbonate" is higher than 27.5 mmol/l because the weak acids in Martis' solution "will be converted by the liver to bicarbonate as a one to one conversion rate" (page 15 of the 3/15/06 arguments; see also paragraphs 9-12 of the 2/9/2006 declaration). Applicant argues at length about this feature, but applicant should read the claims again. The claims mention nothing about an "effective" bicarbonate level. The claims require bicarbonate concentration of the diluted solution, not the in vivo conversion rate/concentration of all the solution components. The Examiner maintains that Martis' teaching is applicable to applicant's claim language.

Applicant argues further that Martis' peritoneal dialysis teaching is not relevant to the present claim set because the present claim set has been amended to recite dialysis concentrate/solution for continuous renal replacement therapy, "which is an all together different process." Applicant is reminded that the invention here is directed to the composition per se. The Examiner has established that the dialysis solution taught and suggested by Martis et al. contains the same components as applicant's. It is not a requirement for a rejection under section 103 that the prior art teaches or suggests the same composition for identical purpose. As long as there is a suggestion or motivation to arrive at the claimed subject matter, the rejection is proper. In re Kemps, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996).

Applicant argues that Martis' calcium range of 0.0 to 4.0 mEq/L would lead to chronic loss of calcium and would need regular supplementation. Applicant then curiously argues that calcium should be present in Martis' solution, calcium would precipitate when heat sterilized, and hence, Martis' disclosure is not enabling. Applicant's assumptions are flawed. Martis' claim 7 explicitly discloses 0.0 mEq/L calcium. 0.0 is pretty exact. It means no calcium since 0.0 is less

than 0.00000000000001 mEq/L. Martis et al. chose the precise claim language of 0.0 mEq/L calcium and that is how the disclosure would have been understood by the ordinary skilled artisan.

For these reasons, this ground of rejection, which includes newly amended and considered claims 18-19 and 21, must be maintained.

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable, *subject to a search update at the time of the next Office action*, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

It is noted for the record that the Examiner has repeatedly and specifically asked applicant about "NORMOCARB." Repeatedly, applicant has been less than informative as to its/their exact content and its/their prior public use, public disclosure and commercial activity. In answer to the Examiner's previous request for information (Office action of 8/11/2005, paragraph bridging pages 12-13), this is what applicant states:

> **Lastly the Examiner reminds applicant about his duty to disclose "all information known to be material to patentability" in this application with respect to NORMOCARB® product information. The Examiner is advised that NORMOCARB® owned by the Assignee was marketed originally by the Assignee consistent with the teachings of Purcell and was based on those teachings. Applicant had previously advised the Examiner of this fact.**

Let the record show that the Examiner still does not know what types of NORMOCARB products were in existence, in public use, disclosed publicly,

and/or involved in commercial activity before 12/20/1999. The Examiner does not have any other means to compel applicant to answer these questions and leaves such issues for post-allowance, if necessary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
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